northern health
the northern way of caring

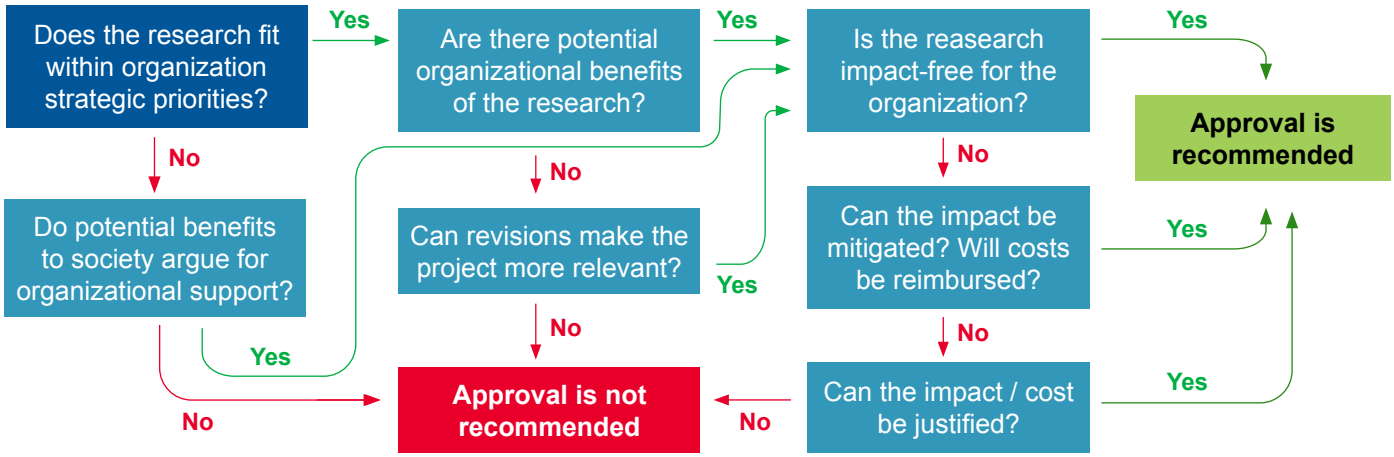
Northern Health Corporate Office
600-299 Victoria Street, Prince George, BC V2L 5B8
Telephone (250) 565-2649, Fax: (250) 565-2640, www.northernhealth.ca

Application for Operational Approval for Research Studies

IMPORTANT INFORMATION FOR APPROVERS

About the decision making process:

- The information required to make a decision can be found in Sections 1 to 3. Section 5 include information needed by the research team that is usually not necessary for approvers to make a decision. You are welcome, however, to review that information too.
- The operational approval decision making process is based on an objective assessment of the study:
  - potential contribution to the organization and/or society; and
  - operational impact on Northern Health (NH).
- Please refer to the flowchart provided below for additional details on how to arrive at a decision:



Adapted from Bowen, Graham, Botting, 2022

About your responsibilities as an approver:

- As operational approver, your signature in this form confirms that:
  - You are the appropriate person to provide operational approval on behalf of NH.
  - Resources required to conduct the research can be provided and the activities can be executed while service delivery is maintained.
  - Cost recovery agreements have been negotiated with the researcher if required.
  - You will communicate to the appropriate people in the organization that the research is happening and is supported by NH.
  - You will support knowledge translation activities.

Where to send the form

- The signed form can be sent by email to Research@northernhealth.ca or fax (250) 565-2640, Attention: Research Review Committee.

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IMPORTANT INFORMATION FOR INVESTIGATORS

About approval process for research studies at Northern Health (NH):

- Research at NH requires the appropriate approvals to proceed:
  - Research Ethics Approval given by NH Review Committee
  - NH Operational Approval
  - An approved NH Information Sharing Agreement (ISA), when the study requests disclosure of personal information (identifying or de-identified).**
  - An approved NH Privacy Impact Assessment (PIA) when the study requests to implement new technology or change existing technology.**

  **The Principle Investigator (PI) is required to complete an NH ISA or NH PIA and submit it to NH Privacy. NH Research will facilitate PI engagement with appropriate NH stakeholders.
- Once all necessary approvals are obtained, the NH Institutional Authorization Letter is issued. Only then the study can commence.
- **Important: this form is only for Operational Approval.** Information on how to submit an ethics application and a visual about NH Research Process Map can be found here NH Research Review Committee | Northern Health.

For additional information about research at NH, please contact the Research Engagement Team (RET) at Research@northernhealth.ca.

About the operational approval process:

- Operational Approvals must be requested and obtained prior to the beginning of the study.
- Submit the completed Operational Approval form by email to Research@northernhealth.ca or fax (250-565-2640, Attention: Research Review Committee).

About privacy requirements (if applicable):

- It is expected that the requirement for an ISA or PIA has been identified during Ethics or Operational approval activity. The work to actually complete an ISA or PIA is expected to occur after Ethics and Operational approval has been received.
- The NH Privacy Office is engaged as part of the research study review process. If there is a need to contact NH Privacy outside of that process, you may do so by sending an email to privacy@northernhealth.ca.

About data requests (if applicable):

- If the project requires secondary data please contact the ID Hub (idhub@northernhealth.ca).

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SECTION 1: STUDY DETAILS

1. Project Title:

2. Specify current status of research ethics review process:

- ☐ Application submitted and pending approval
- ☐ Ethics approval obtained

3. Purpose of Research (provide a brief description in plain language):

4. What benefits would this research bring to NH and/or society?

5. Source(s) of funds to conduct the study:

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SECTION 2: OPERATIONAL IMPACT

6. Provide a specific list of NH facilities[1], departments and/or communities in which your study will be conducted.

7. Please select the NH services or support required to conduct this research (choose all that apply and provide a description):

Service or support required	Description
☐ Requesting approval to post an advertisement/recruitment material	
☐ NH staff will be invited to participate in the study	
☐ If staff will be invited to participate in the study, specify the following: • How participants will be identified and contacted? • Number of participants • Time commitment • Participation options (e.g. online, in-person, outside of work, at work etc.) • What will be required of participants? (e.g. participate in a survey, focus group etc.)	
☐ NH staff will be required to assist in the conduct of the study. Please provide details of what will be required.	
☐ If staff will be required to assist in the conduct of the study, specify the following: • Number of staff • Time commitment	
☐ Space(s) in NH sites is required for this study	
☐ Information owned or maintained by NH is required for this study: • In what year will access be required? (For multi-year studies, which year will you require this information/data?) • If the information is in paper-based charts, will review/audit of the charts directly by the research project team be required? • Preferred method to access, receive, or work with NH data?	

[1] For investigators: Information about facilities can be found here Locations | Northern Health.

☐ NH-patients involvement (specify relevant demographics or target groups)	
☐ Community involvement (specify relevant details/characteristics of the community)	
☐ Equipment owned or maintained by NH is required for this study	
☐ Other direct involvement or requirement of support or service from NH department(s) or staff.	

8. Are participating staff members being compensated for their involvement in the project?

☐ Yes ☐ No ☐ N/A

If yes, please indicate the type of compensation to be received, how much and for what activity:

9. Will NH be compensated for the costs it may incur by supporting the study?

☐ Yes ☐ No ☐ N/A

If yes, explain how:

10. Does the study/research include a Knowledge Translation (KT)[2] component?

☐ Yes ☐ No

11. If your study includes a KT plan, please describe:

[2] CIHR explains KT as a process of summarizing, distributing, sharing, and applying the knowledge developed by researchers to improve the health of Canadians, and strengthen the health care system through the use of more effective health services, products, and standards of practice.

Integrated KT is a collaborative approach in which researchers and knowledge users (e.g. policymakers, clinicians) work together to design and implement the study, develop tools, interpret findings, and disseminate research results. This approach is intended to produce research findings that are more likely to be relevant to, and used by, the end users.
(Adapted from: https://cihr-irsc.gc.ca/e/48952.html).

SECTION 3: COVID RISK MANAGEMENT & IN-PERSON ACTIVITIES

12. Are you planning to conduct in-person activities?

☐ Yes ☐ No

If yes, please describe the in-person activities that will be conducted:

13. If applicable, identify the locations where the in-person activities will be conducted?

14. If applicable, what measures will be implemented to minimize risks from COVID-19?

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SECTION 4: OPERATIONAL APPROVERS' SIGNATURES

Name of Department/Site/Community:
Person Responsible for Institutional Authorization: Name: Title: Email: Signature: Date:

Name of Department/Site/Community:
Person Responsible for Institutional Authorization: Name: Title: Email: Signature: Date:

Name of Department/Site/Community:
Person Responsible for Institutional Authorization: Name: Title: Email: Signature: Date:

SECTION 5: GENERAL INFORMATION

15. Principal Investigator:

Name:

Email:

Title:

Program/Department/School:

Institution:

Have you completed the following training?

☐ TCPS ☐ GCP

If this is a clinical study, please send your signed CV, practice license and GCP/TCPS certificates to Research@northernhealth.ca.

16. Supervisor Name (if researcher is a student or resident/repeat the PI information if applicable):

Name:

Email:

Title:

Program/Department/School:

Institution:

Signature:

Have you completed the following training?

☐ TCPS ☐ GCP

If this is a clinical study, please send your signed CV, practice license and GCP/TCPS certificates to Research@northernhealth.ca.

17. Co-Investigator(s) (or Local PI/Site Investigator(s):

Name:

Email:

Title:

Program/Department/School:

Institution:

Signature:

Have you completed the following training?

☐ TCPS ☐ GCP

If this is a clinical study, please send your signed CV, practice license and GCP/TCPS certificates to Research@northernhealth.ca.

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18. Primary Contact (if different from Principal Investigator):

Name:

Email:

Title:

Program/Department/School:

Institution:

Have you completed the following training?

☐ TCPS ☐ GCP

If this is a clinical study, please send your signed CV, practice license and GCP/TCPS certificates to Research@northernhealth.ca.

19. Specify the Ethics Board of Record for the study:

20. Identify the ethics application ID/file number:

21. Please confirm that you are aware that research ethics approval of this study must be granted by NH Research Review Committee:

☐ Yes ☐ No

22. What are the outcomes of the Privacy assessment for this study?

- ☐ Not applicable for this study (proceed to question 23)
- ISA is required: ☐ Yes ☐ No
- PIA is required: ☐ Yes ☐ No

23. Is the purpose of the study to satisfy educational requirements such as course work, Master or PhD thesis?

☐ Yes ☐ No

24. Please select up to 3 categories that best describe your study:

☐ Acute care	☐ Health human resources	☐ Patient-oriented research
☐ Cancer	☐ Home care	☐ Perinatal
☐ Child and youth	☐ Indigenous health	☐ Pharmacy
☐ Chronic disease	☐ Information Technology	☐ Primary health care
☐ Critical care (ED, trauma)	☐ Medication management	☐ Public and population health
☐ Diagnostics	☐ Mental health and addictions	☐ Rehabilitation
☐ Dietetics	☐ Nursing	☐ Surgical services
☐ Elder care	☐ Palliative care	☐ Other:

25. Please select the most appropriate health research category according to the definitions provided by the Canadian Institute for Health Research Themes.

- ☐ Biomedical
- ☐ Clinical
- ☐ Health Services
- ☐ Medication management
- ☐ Social, Cultural, Environmental, and Population Health

26. For clinical studies[3], please select all that applies:

- ☐ Observational
- ☐ Clinical Trial
- ☐ Investigator-initiated
- ☐ Sponsor-initiated; specify the sponsor:

27. If there is a KT plan in place for this study, please identify the knowledge users in Northern Health:

Name: Email: Department: Site/Location: Role:
Name: Email: Department: Site/Location: Role:

28. Does the funding agency and/or institution requires KT activities?

- ☐ Yes
- ☐ No
- ☐ N/A

29. Please describe the rationale and interest to participate in Knowledge Translation activities and potential time commitment to it?

[3] Clinical trials should submit a fee schedule to Research@northernhealth.ca.
Please, remember that industry sponsored trials require a 40% overhead fee and investigator-initiated trials require a 15% overhead fee.

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SECTION 6: INVESTIGATORS' SIGNATURE PAGE

By submitting this form, I, the study Principal Investigator agree to:

- ☐ Submit a copy of the final study to be archived by NH Research Review Committee and placed at the NH Library and sponsoring facility use;
- ☐ Submit a copy of the final report to NH Research Review Committee (research@northernhealth.ca) at project completion; and
- ☐ Contact the Research Engagement Team (research@northernhealth.ca) upon study completion to plan the presentation of the results to relevant stakeholders.

By submitting this form, I, the study Principal Investigator also understand that:

- ☐ NH maintains a database of research undertaken in the health authority; and
- ☐ Upon approval of my research application by the NH Research Review Committee, the following information will be posted on the NH website and Research Annual Report: project title, names and institutions of Investigators, location of research (sites), name and title of NH operational approval manager(s), and project start and completion dates.

Date: **Principal Investigator's Signature:**